UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,466	09/19/2006	Mariusz W. Szkudlinski	TROP-001/01US 304828-2046	9091

58249 7590 09/04/2009

COOLEY GODWARD KRONISH LLP
ATTN: Patent Group
Suite 1100
777 - 6th Street, NW
WASHINGTON, DC 20001

EXAMINER	
BORGEEST, CHRISTINA M	
ART UNIT	**PAPER NUMBER**
1649	

MAIL DATE	DELIVERY MODE
09/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,466	SZKUDLINSKI ET AL.	
	Examiner	Art Unit	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-137* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-137* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Upon reconsideration, the Restriction requirement mailed 25 February 2009 is vacated, as it contained errors in Part A. Any inconvenience to the Applicants is deeply regretted. The restriction set forth below replaces that which was mailed 25 February 2009.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

PART A - Inventive Groups

Group I, claim(s) 1-67, 84-99, 102-115, 118-129, 132, 133, 136-137, drawn to modified follicle stimulating hormone (FSH) or superactive FSH with increased potency and/or half life, nucleic acids encoding said FSH variants, vectors comprising said nucleic acids encoding said FSH variants and methods of administration of said modified FSH variants.

Group II, claim(s) 68-71 and 74-77, drawn to methods of diagnosing ovulatory dysfunction or other types of female infertility.

Group III, claim(s) 68-71 and 74-77, drawn to methods of treating ovulatory dysfunction or other types of female infertility.

Group IV, claim(s) 68, 72 and 79, drawn to methods of diagnosing male factor infertility.

Group V, claim(s) 68, 72 and 79, drawn to methods of treating male factor infertility.

Group VI, claim(s) 68 and 78, drawn to methods of diagnosing male pattern baldness.

Group VII, claim(s) 68 and 78, drawn to methods of treating male pattern baldness.

Group VIII, claim(s) 68 and 80, drawn to methods of diagnosing pituitary failure.

Group IX, claim(s) 68 and 80, drawn to methods of treating pituitary failure.

Group X, claim(s) 68 and 81, drawn to methods of diagnosing ovarian carcinoma.

Group XI, claim(s) 68 and 81, drawn to methods of treating ovarian carcinoma.

Group XII, claim(s) 68 and 82, drawn to methods of diagnosing testicular carcinoma.

Group XIII, claim(s) 68 and 82, drawn to methods of treating testicular carcinoma.

Group XIV, claim(s) 83, drawn to a method of reducing ovarian hyperstimulation comprising administering a modified FSH with increased half-life, followed by subsequent administration of a second modified FSH, wherein the activity of said FSH is decreased.

Group XV, claim(s) 100, 116, 130, drawn to methods of administration of a modified FSH with increased potency and/or half life or superactive FSH and/or half life, and additionally, followed by subsequent administration with human chorionic gonadotropin (hCG).

Group XVI, claim(s) 101,117, 131, drawn to a method of administration of a modified FSH with increased potency and/or half life or a superactive FSH wherein said superactive FSH contains a wild-type alpha-subunit.

Group XVII, claim(s) 134-135, drawn to modified FSH wherein there is a decrease in plasma half-life and absorption as compared to wild type FSH.

PART B - Modified FSH α-subunit (shows the substitutions to SEQ ID NO: 1)

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

MODIFIED FSH α-SUBUNIT (SHOWS THE SUBSTITUTIONS TO SEQ ID NO: 1)

1. E14R and N66R
2. E14R and G73R
3. P16R and Q20R
3. Q20R and P21R
4. P16R, Q20R and P21R
5. E14R, Q20R and G73R
6. N66K, G73K and A81K
7. E14R, N66R and G73R
8. Q13R, E14R, P16R and Q20R
9. Q13K, E14K, P16K and Q20K
10. E14R, Q20R, P21R, N66R and G73R
11. E14R, P16R, Q20R, N66R and G73R
12. Q13K, E14K, P16K, Q20K, N66K and G73K
13. E14R, P16R, Q20R, P21R, N66R and G73R
14. A85E
15. A85D

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Part C - Additional Modifications to FSH

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

ADDITIONAL MODIFICATIONS TO FSH

1. Substitution in β-chain consisting of E4R of SEQ ID NO: 2
2. N-terminal extension of either SEQ ID NO: 3 or SEQ ID NO: 4
3. Substitution in β-chain consisting of Y58N
4. Substitution in β-chain consisting of V78N
5. Insertion of SEQ ID NO: 5 or SEQ ID NO: 6
6. Insertion of SEQ ID NO: 7 or SEQ ID NO: 8

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Part D – Reasons Why Unity Is Lacking

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

First, rules governing 371 National Stage provide for examination of the first named product, the first named method of making said product and the first named method of using said product, but do not provide for multiple products. The composition of Group I can have any of the 15 mutations of Part B and any of the 6 mutations of Part C. The 15 possibilities for the first mutation added to the 6 possibilities for the second mutation equals a total of 21 possible compositions. The 21 possible compositions claimed in Group I lack unity of invention, because each of the 21 possible compositions represents a different contribution to the art, and do not share a special technical feature. Second, Groups III-XIV of diagnosing or treating female factor infertility, male factor infertility, male pattern baldness, pituitary failure, ovarian carcinoma or testicular carcinoma do not share any common technical features because the patient populations are so diverse. Further, diagnosing disease does not share common steps with treating disease, thus does not share a special technical feature. Note 37 CFR 1.475, which sets forth the rules governing unity of invention. In the instant case, the multiple methods of treatment claimed do not represent one of the listed categories of invention considered to have unity of invention, for instance, they do not represent a single product, a process specially adapted for the manufacture of the said product, and a use of the said product. Note also 37 CFR 1.475(e), which states that the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. Third, Group XV is drawn to administration of a modified FSH with decreased activity, whereas Groups III-XIV are drawn to methods of

administering a modified FSH with greater activity. Groups III-XIV encompasses administration of FSH with any of the mutations of Part B and Part C, thus encompasses the administration of 20 different compositions multiplied by the number of different methods. Fourth, Group XV has the additional step of administering hCG. Fifth, Group XVI is drawn to administration of a modified FSH with a wild type α subunit, thus encompasses a modified FSH with any of the modifications listed in Part C, thus encompasses administration of 6 different compositions. Finally, Group XVII is drawn to a modified FSH that has a decrease in half-life and absorption as compared to wild-type, thus does not share a common technical feature with a modified FSH with ten-fold increased potency.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Note that the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP

§ 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is (571)272-4482. The examiner can normally be reached on 8:00am - 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Borgeest

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646